IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SANOFI, et al.,	)	Trial Volume 3
	)	
Plaintiffs,	)	
	)	C.A. No. 14-264-RGA
v.	)	14-265-RGA,
	)	14-292-RGA,
GLENMARK PHARMACEUTICALS,	)	14-1434-RGA
INC., USA, et al.,	)	
	)	
Defendants.	)	

Thursday, June 9, 2016
8:35 a.m.
Courtroom 6A

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE RICHARD G. ANDREWS,
United States District Court Judge

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL
BY: DEREK J. FAHNESTOCK, ESQ.

-and-

FITZPATRICK, CELLA, HARPER & SCINTO
BY: WILLIAM E. SOLANDER, ESQ.
BY: DANIEL J. MINION, ESQ.
BY: JAMES TYMINSKI, ESQ.

Counsel for the Plaintiffs

APPEARANCES CONTINUED:

PROTOR HEYMAN ENERIO, LLP
BY: DOMINICK T. GATTUSO, ESQ.

-and-

ALSTON & BIRD, LLP
BY: NATALIE C. CLAYTON, ESQ.
BY: CHRISTOPHER L. MCARDLE, ESQ.
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Counsel for the Defendant Watson

ABRAMS & BAYLISS, LLP
BY: JOHN M. SEAMAN, ESQ.

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BY: MAUREEN L. RURKA, ESQ.
BY: JULIA M. JOHNSON, ESQ.
BY: LOREN G. RENE, ESQ.

Counsel for the Defendant Sandoz

THE COURT: Good morning, everyone. Please be seated. Ms. Clayton, I guess.

MS. CLAYTON: I think there's still some housekeeping for Plaintiffs first.

MR. SOLANDER: Good morning, Your Honor.

THE COURT: Good morning, Mr. Solander.

MR. SOLANDER: So we left off last time with the argument on Doctor Ardehali and his testimony and I'd just like to make a brief offer of proof, if I can.

THE COURT: All right.

MR. SOLANDER: We would offer -- if permitted, we would have offered the testimony of Hossein Ardehali, MD, PhD, who is a cardiologist at Northwestern University and we would have offered him in support of the point that the art was too unpredictable for a person of ordinary skill in the art in 2008 to have expected Dronedarone to reduce cardiovascular hospitalizations without the benefit of the results of the Athena study. Your Honor, I put

a sticker on this. I understand it's not evidence. It's PTX-555, just in case we need to refer to it at some later point.

THE COURT: What is that?

MR. SOLANDER: You asked me to submit the testimony in writing. It's just a highlighted transcript.

THE COURT: All right. So actually so I'll take that. And so why don't we do this, because when I was back after we recessed yesterday, it occurred to me I was kind of curious as to why nobody was citing much in the way of authority. So whenever you're writing me these brief letters you're going to be writing me about these other issues, if you have anything that has any actual case authority on the issue, you can supply that too. And if for some reason or other the case authority tells me I was wrong in the ruling I gave last night, then I will say so and actually read the transcript and incorporate it into whatever it is that I'm doing.

MR. SOLANDER: If Your Honor makes that ruling, then we will have to submit both

sides. I'm only offering the things we wanted to get into evidence not the counters, of course, but if Your Honor makes that ruling, the counters will come in and we'll supply it.

THE COURT: Why don't you make your offer. I'll let Ms. Clayton at a later time put in whatever counters she wants unless she's ready to do that right now.

MR. SOLANDER: I think the better way to do it is if we can attach the entirety of it to this letter.

THE COURT: That will be fine too.

MS. CLAYTON: That's fine.

MR. SOLANDER: Okay. So would you like a copy of what it is right now?

THE COURT: No. If you're going to attach a copy, you know, that will count as being --

MR. SOLANDER: Okay. At the moment I'm satisfied I've preserved it for the record.

THE COURT: I think you have too.

MR. SOLANDER: Okay. Oh, Your Honor, we rest our rebuttal case on the issue of

validity. Thank you.

THE COURT: Okay. Thank you. Ms. Clayton. Sorry.

MS. CLAYTON: This morning, Your Honor, we're going to have a short deposition clip.

THE COURT: Okay.

MS. CLAYTON: It's approximately 15 minutes. 12. Even less. Followed by Doctor McDuff.

THE COURT: Okay.

MS. CLAYTON: And Mr. McArdle will be introducing the deposition.

THE COURT: Okay.

MR. McARDLE: Good morning, Your Honor. Defendants are going to play portions of the deposition of Mr. John Fritchman. Mr. Fritchman was deposed on July 29th, 2015, by counsel for Defendants. Mr. Fritchman is a current Sanofi employee and is in charge of the team that markets Multaq in the United States. As Ms. Clayton indicated, the clip will run for approximately 12 minutes with 10 minutes being allocated to Defendants and two minutes to be

allocated to Plaintiffs. I'm going to bring up the highlighted portions and copies of the exhibits for Your Honor.

THE COURT: Okay. That's good. Thank you.

(Video playing.)

Q. Good morning Doctor Fritchman. Is it Doctor or Mr.?

A. Mr.

Q. Okay. Could you please state your name for the record?

A. John Fritchman.

Q. Okay. Could you state your position currently?

A. I am the brand lead for Multaq in the United States for Sanofi.

Q. Okay. And what does that mean, brand lead?

A. I am the -- I'm in charge of the marketing team that markets Multaq in the United States.

Q. Okay. Let's start from the other end. After your high school education, can you tell me about any college or graduate school

that you were involved with?

A. I attended -- for my bachelors degree, I attended United States Military Academy at West Point, and then I attended -- I received an MBA from Regis University.

Q. What was your degree from West Point in?

A. It was in mathematical science.

Q. Okay. Did you obtain any additional -- did you take any additional courses after graduating from West Point or Regis University that involve -- that have a technical nature?

A. No.

Q. What does market shaping mean to you?

A. It could mean a lot of things. I don't know what the context is in this document.

Q. What -- what are some of the things that it could mean?

A. You could be -- it could be that you are trying to establish, for example, rhythm as an important component to treatment of afib.

Q. And what does that mean?

A. So there are three components to treatment of afib: There's anticoagulation, there's rate control and there's rhythm control. And it could mean that as a product that's an antiarrhythmic agent that's coming into a generic market, that they want to elevate the treatment of rhythm alongside of the other components of treatment of afib.

Q. Would it be a promotion effort for that use?

A. There will than some promotion, yes.

Q. To elevate it over other generics in the market?

A. Not necessarily. It's more important to elevate the treatment of rhythm in general.

Q. Why?

A. Because as you saw in their documents, you have anticoagulation, you have rate and you have rhythm. So those components, physicians, they're going to have to make decisions and -- clinical decisions as to how they treat afib. So if you're going to be --

again, it's important to have the rhythm component for the patient as much as it is anticoagulation or rate potentially.

Q. Do you physicians and healthcare providers review a label in consideration whether to prescribe Multaq to patients?

A. Yes.

Q. Would it be fair to say that the content of that label is the major driver for prescribing Multaq?

A. The label is the -- is the guide by which they should prescribe a product.

Q. Okay.

A. Yes.

Q. And you said is the guide by which they should prescribe it. Can they prescribe it any other way?

A. That's -- again, that's up to the -- up to the physician. Again, what we're guided by is what we can promote. So we can promote basically only what's in the label.

Q. Is the goal of marketing to elevate the use of your product?

A. Marketing is -- is to educate the

physicians and to ensure that -- I mean, again, it's a myriad of things, but it's again, to ensure that they understand how to appropriately use Multaq for the appropriate patient for atrial fibrillation.

Q. I'm going to hand you a document that we're going to mark as Defendant's Exhibit 99.

Do you have any reason to doubt this is a Sanofi document?

A. No.

Q. If you turn to Page 7, below that, that page is entitled, however, there is room for a new AF treatment as physicians' satisfaction with AF -- satisfaction with current AF treatments is mediocre, 6 to 7 out of 10, whatever the treatment. And there it breaks down these drugs by rhythm and rate and identifies the rhythm agents as amiodarone, flecainide, sotalol, propafenone and the rate agents as digoxin, carvedilol, diltiazem and verapamil. Do you see that?

A. Yes.

Q. Am I describing that correctly?

A. Yes.

Q. Okay. If you could turn to page 9. A little bit earlier we talked about a similar discussion, but at the top of that page 9 it says the main source of Multaq business at launch will be treatment switch, 86 percent. And there it has a bar chart, it says initiation 4 percent, switch 86 percent, add-on 10 percent, Rx type equals 100 percent. So 4 percent discusses initiation.

Is it fair to say that's initiation of Multaq in patients who were not being treated before?

A. I'm not sure of the definition.

Q. Okay. If you look below that bar, it says previous therapy all the way to the right?

A. Okay.

Q. And then, if you look to the left of that bar, it says previous therapy: None, and then it says 4 percent.

A. Okay.

Q. So that means there's 4 percent of the patient population that had no therapy. If

you look above that, it says initiation 4 percent. Is it fair to say initiation means the start of new therapy involving Multaq?

A. Yes.

Q. And then on the top bar, it says switch 86 percent. And as we discussed earlier, is that -- is it fair to say that switch is switching from another antiarrhythmic agent to Multaq?

A. No.

Q. What does switch mean to you?

A. Switch means -- could mean switch from anything that they're being prescribed potentially to Multaq. It could mean a myriad of things. And I think the chart -- the chart as it's described here shows a switch from rate agent or it could be a combination thereof from another rhythm. So it doesn't -- it could depend.

Q. Fair enough. So switch 86 could be inclusive of the rate agent or a rate agent and a rhythm agent; is that correct?

A. Yes.

Q. I'm going to give you a document

that is -- we're going to mark as Defendant's Exhibit 100. Do you have a reason to doubt this is a Sanofi document?

A. No.

Q. Is it fair to draw the conclusion that Multaq does not have a better efficacy than amiodarone from this Sanofi document?

A. No, I don't think it is fair to say.

Q. Why not?

A. Because you don't -- there's multiple things that go into it. I don't know everything that's gone into this document.

Q. I'm going to give you a document we're going to mark as Defendant's Exhibit 111. Okay. You'll take a look at this. I'm sure you're very familiar with this. This is the Multaq Dronedarone label prescribing information. Am I accurate in my description?

A. This was the label that was revised in 2011.

Q. Yeah. I was just going to say this is the August 2011 revised label. But I'm accurate, this is the prescribing information as

of that date?

A. Yes.

Q. Okay. And if you look at the indications and usage there on the first page, it includes the associated cardiovascular risk factors, doesn't it?

A. Yes, it does.

Q. And then if you flip the page to page 2, you'll see it says full prescribing information at the top and then, under number 1, it also mirrors the same associated cardiovascular risk factors; is that correct?

A. Yes.

Q. Okay. You can set that aside. I'm going to give you a document we're going to mark as Defendants Exhibit 112.

Now, you'll notice this is also Multaq prescribing information. In the bottom right-hand corner, it says revised December 2011. This is while you were in charge of Multaq. So this was during your -- your involvement with Multaq; is that accurate?

A. No, this isn't when I was in charge. This is when I was a product manager on

Multaq.

Q. All right. Mr. Fritchman, is it accurate to say that there are a number of antiarrhythmic drugs on the market, both in the rhythm class and the rate class?

A. There are -- there are many -- there are various products that are used to treat atrial fibrillation. There are several antiarrhythmic agents and then there are obviously several rate agents that are used in the treatment of afib, yes.

Q. So there were -- I guess it's accurate to say, also, there was no absence of products to treat atrial fibrillation?

A. I don't understand the question about when you -- how you refer to it as an absence of products.

Q. Was there any long-felt need that Multaq had to be on the market or was there -- are -- or were there already products used to treat atrial fibrillation?

A. There was a significant unmet need in the marketplace in the treatment of atrial fibrillation.

Q. And what was that?

A. There were many. The consideration for treatment for afib is that the -- the class of drugs utilized have some significant side effects associated, particularly in the rhythm component.

(Video complete.)

MR. McARDLE: Your Honor, just a few housekeeping matters. We want to move in JTX-80, JTX-81 and JTX-92 from Mr. Fritchman's deposition testimony.

MR. ROTHMAN: No objection.

THE COURT: All right. Those three are admitted without objection.

MR. McARDLE: And then we have a few other -- a few other exhibits we're going to be moving in as well. There's DTX-78, which is your claim construction opinion.

THE COURT: You don't need to move the claim construction opinion into evidence.

MR. McARDLE: Well, we want it on the record for appeal, Your Honor.

THE COURT: It's on the record.

MR. McARDLE: Okay. The

transcript, is that -- do we need to move that in?

THE COURT: The transcript of what?

MR. McARDLE: Of the claim construction hearing, Your Honor.

THE COURT: No.

MR. McARDLE: Okay. Well, you can tell me if I'm mistaken in the next few as well. Portions of the '167 Patent file history, just specifically the application and reasons for allowance. That's DTX-331. DTX-332 is exhibits or sorry excerpts from the joint claim construction chart, specifically.

THE COURT: The Markman issues are preserved without doing anything at trial.

MR. McARDLE: Okay. Okay. Your Honor. Thank you, Your Honor.

THE COURT: Okay. Thank you, Mr. McArdle.

MR. SOLANDER: Your Honor, with respect to the patent file history of the patent that's in this case, which I understand he was just offering, I suppose that can come in, I

don't see a problem with that --

THE COURT: Well, but, you know, it drives me crazy people just admitting documents that have no apparent connection to anything that's actually a trial issue.

MR. SOLANDER: I'm not offering it. I'm not offering it. I was just saying I don't want excerpts, I want the whole thing.

MS. CLAYTON: Your Honor, there is one document that is on that list that was not part of the claim construction.

THE COURT: Okay.

MS. CLAYTON: And that is the DTX-331, the excerpts of the '167 Patent file history.

THE COURT: What is the relevance to the trial we're having?

MS. CLAYTON: The relevance to the trial is to show the original scope of the claims that Plaintiffs or the patentee requested with the patent office, and then the ones they eventually obtained that were much narrower.

THE COURT: Did some witness refer to this?

MS. CLAYTON: I mean, it was referred to during Doctor Radzik's deposition, the professionals, and then during the opening, I know we saw the original scope and then obviously we've seen the currently narrowed claims quite frequently from -- I mean, the narrow claims that ultimate issues were discussed by almost every witness.

THE COURT: And this proves what?

MS. CLAYTON: It's just to show that originally they had requested a much broader invention and then they narrowed that invention during prosecution.

THE COURT: That proves what?

MS. CLAYTON: Well, a couple of things, Your Honor. First, there is an argument here that they are not entitled to the original priority date, which Doctor Radzik was talking about.

THE COURT: Okay. That's good. I'll let it in for that.

MR. SOLANDER: Your Honor, I don't know that those excerpts go to that at all. She was talking about an office action in the

allowance.

THE COURT: Well, that would be -- so, you know, I'm probably happy to have the entire file history admitted into evidence.

MS. CLAYTON: We don't object to that. We were just trying to focus on what we needed.

THE COURT: Here's what we're going to do. I'm more and more appreciating the stuff that Judge Robinson does. When we have the briefing after this, if you don't mention in the briefing all these exhibits we're introducing, I'm going to strike them from the record. I mean, because it's just -- because I do think that a lot -- I had my doubts as to how many of these things are actually being admitted for anything other than they were mentioned, so let's admit it. It's not a rule that if you mention an exhibit you have to admit it into evidence. But anyway, prosecution history sounds plausible to me. There's no objection. It's admitted. You're going to give me DTX-331?

MR. SOLANDER: That's not the entirety of the prosecution history, that's my

point. We can figure out that number and tell Your Honor. It's not a problem.

THE COURT: Okay. All right. Are we up to Doctor McDuff?

MS. CLAYTON: Yes. At this time Defendants call Doctor McDuff to the stand.

Your Honor, may we approach the Court.

ROBERT DeFOREST McDUFF,

the deponent herein, having first been duly sworn on oath, was examined and testified as follows: BY MS. CLAYTON:

Q. Good morning, Doctor McDuff.

A. Good morning.

Q. Would you please state your name for the record?

A. DeForest McDuff.

Q. And very briefly, what were you asked to testify about here today?

A. I was asked to testify about the alleged commercial success of Multaq.

Q. And have you prepared slides today to assist with that testimony?

A. I have.

Q. And have you prepared a slide that briefly summarizes your educational and work history?

A. Yes, that's the next slide.

Q. Could you briefly, using this slide, describe for us your educational and work history?

A. Yes, I have bachelors degree in mathematics and economics from the University of Maryland. I have a masters degree and a PhD in economics from Princeton University. I work as an economic consultant at a company called Intensity. I'm a vice president there and head of the Boston office. I have more than 10 years of experience in consulting, finance and economic research.

Q. And has your work involved being an expert in pharmaceutical litigation cases?

A. Yes, I worked on more than 30 cases.

Q. And have you dealt with issues related to commercial success in pharmaceutical litigations?

A. Yes, in more than 20 cases.

Q. And if you look at JTX-234, which is in your binder.

A. Okay.

Q. Is this your CV?

A. Yes, it is.

Q. Is it current and accurate?

A. Yes, as of January 2016.

MS. CLAYTON: And Your Honor, we would tender Doctor McDuff as an expert witness in economic analysis as it pertains to commercial success.

MR. ROTHMAN: No objection.

THE COURT: You may proceed.

BY MS. CLAYTON:

Q. What were you asked to do in this case, Doctor McDuff?

A. I was asked to evaluate the alleged commercial success of Multaq. I was also asked to review the reports submitted by Mr. Tate and Doctor Reiffel as they pertain to commercial success.

Q. And what is your understanding of commercial success?

A. Commercial success is one of the secondary considerations that's used in the evaluation of obviousness or can be used. The idea is that if a product is commercially successful and it were obvious it would have been brought to market sooner in response to market forces.

Q. How did you develop that understanding?

A. That's based on my experience as an economist working on a number of cases of this type and discussions and review of case law over the years.

Q. And have you reached conclusions related to the commercial success of Multaq in this case?

A. I have.

Q. And have you prepared a slide that summarizes those opinions?

A. Yes.

Q. If you could go to the next slide. So using this slide, can you briefly summarize for the Court what your opinion is related to Multaq and its commercial success are?

A. Yes, number 1, Multaq has not been a commercial success. Number 2, there were disincentives for development in the form of blocking patents and exclusivity that weaken the economic relevance of commercial success here. And number 3, Plaintiffs have not demonstrated a nexus to the patents in suit.

Q. And how did you go about developing these opinions for this case?

A. I approached this case the same way as all my cases. I analyze sales data, profit data, market analysis, internal Sanofi documents, deposition testimony, things of that nature.

Q. And are there some primary factors that led you to your conclusions in this case?

A. Yes, you can see that on the next slide.

Q. And can you just briefly describe for us what each of these points is?

A. Yes. Number 1, Multaq sales are low. Number 2, Multaq has a low market share in a variety of market definitions. Number 3, Multaq has future limited opportunity. In other

words, sales are unlikely to grow significantly from here. Number 4, Multaq has not earned an economic profit and is unlikely to ever earn an economic profit. Number 5, blocking patents and exclusivity limit the economic relevance of commercial success here. And number 6, Plaintiffs have not demonstrated a nexus between the '167 Patent and sales in the use of Multaq.

Q. So let's go through these in order and let's start with the low sales. Now, did you evaluate the Multaq sales in this case?

A. I did.

Q. And have you created a demonstrative that shows those sales through launch?

A. Yes.

Q. If we could look at slide 6 from your demonstratives, what is this slide showing us?

A. This slide shows worldwide Multaq sales from 2009 to 2015. As you can see, they grew to around $350 million.

Q. And what is the -- from 2011 and 2015, what are we seeing there for the market

sales for Multaq?

A. Well, they grew in early years but since 2011 they have been relatively flat and controlling for inflation they're actually declining in recent years.

Q. And in particular, what are we seeing between the years of 2014 and 2015?

A. Well, that's the decline that I was talking about. You can see the decline here in nominal terms. Controlling for inflation it's even greater.

Q. And what are the level of sales to date tell you about Multaq?

A. Well, $350 million isn't that significant, not in the pharmaceuticals industry. And we've got some -- I'll discuss that more on the next slide.

Q. Now, what underlying data did you rely on in creating this slide?

A. These sales come from the Sanofi public filings to investors, they are 20F's.

Q. Okay. And if you could quickly look at DTX-3, DTX-211, DTX-330A, JTX-148A, JTX-149B, JTX-150B, JTX-151B and JTX-152B. Is

that the information related to the calculation you performed here and the underlying data you relied on?

A. Yes.

MS. CLAYTON: And Your Honor, we would offer into evidence -- some of these have already been moved in, but we would offer DTX-211, which has not been moved in. DTX-330A, JTX-149B, JTX-150B, JTX-151B and JTX-152B.

MR. ROTHMAN: No objection.

THE COURT: All right. Admitted without objection.

BY MS. CLAYTON:

Q. Are you familiar with the term blockbuster drug?

A. I am.

Q. And what does that term mean?

A. It's a term that's used in the industry that refers to a drug that has more than a billion dollars in sales in a calendar year.

Q. And is Multaq a blockbuster drug?

A. It's not.

Q. And what is the relevance of

comparing Multaq to a blockbuster drug?

A. Well, the relevance or the purpose is to try to get some benchmarks for evaluating whether Multaq is a success. It's not required that a drug be a blockbuster in order to be a commercial success, but it is one benchmark that's used in the industry to describe a successful or a profitable product.

Q. And did you also compare the Multaq sales to other benchmarks in the industry?

A. Yes, I did.

Q. And have you also created a demonstrative to illustrate this?

A. Yes, that's the next slide.

Q. If we can take a look at slide 7. Can you describe for us what you're showing on this chart?

A. Yes, this slide shows Multaq sales in the context of the broader industry. So this is from peer-reviewed published economic literature on returns to pharmaceutical research and development. And there are four lines here. The first is 1st Decile drugs, the second is 2nd

Decile, the third is mean or average drug sales and the 4th in red is Multaq at the bottom.

Q. And when you say 1st Decile, what does that mean?

A. That refers to drugs that are in the top 10 percent, so from the 90th percentile to the 99th percentile.

Q. And 2nd Decile?

A. Those are in the second 10 percent, so from the 80th percentile to the 89th percentile.

Q. Okay. How does Multaq compare to those in the mean?

A. Multaq is significantly less than 1st Decile drugs. As you can see, 1st Decile drugs exceed a billion dollars a year by the fourth year on the market and grow to roughly $2.5 billion per year. 2nd Decile drugs grow to about 8- or $900 million at their peak level. Both of these types of drugs are really the industry drivers of profitability. It's only the top three deciles of drugs that actually turn an economic profit on average. Multaq lies below the average drug or the mean drug. And

this is important because it's known in the literature that average drugs tend to be about break even from economic perspective. In other words, the profits just about compensate for the cost of commercialization, but not more. So the fact that Multaq is below the average indicates that it's unlikely to become economically profitable.

Q. Now, it looks like you obtained the chart at the first, second and mean lines from an article; is that right?

A. Yes.

Q. And if you turn to JTX-241, is that the article where you obtained that information from?

A. It is, yes.

MS. CLAYTON: And Your Honor, we'd offer JTX-241 in evidence.

MR. ROTHMAN: No objection.

THE COURT: All right. Admitted without objection.

BY MS. CLAYTON:

Q. And the mean for Multaq or the line for Multaq, where did you get that

information?

A. That information comes from the Sanofi 20F's from the previous slide and they have been adjusted for inflation to put them on an apples to apples basis relative to these lines from the literature.

Q. Now, based on the chart and this data here, does Multaq appear to be a commercial success in your opinion?

A. No.

Q. And why not?

A. Well, as indicated, Multaq sales just aren't that significant, not in the pharmaceuticals industry. And in particular, lying well below other profitable drugs and lying below even break even drugs in terms of the average. It's unlikely to turn an economic profit.

Q. All right. Now, let's move onto the second topic that you had in your slides, low market share. And what is market share?

A. Market share is a measure of use of a particular product divided by the total use in the market.

Q. And why are market shares relevant for commercial success?

A. They're relevant because they provide another comparison or another benchmark to competitive drugs or drugs in the same market.

Q. And are there two different ways to analyze market share via revenue and via prescriptions for pharmaceuticals?

A. There are, those are both used in the pharmaceuticals market.

Q. And were you here for Mr. Tate's testimony yesterday?

A. I was.

Q. And as part of that, did he do an analysis of market share in his testimony?

A. Yes.

Q. And did he do a market share for both revenues and for total prescriptions?

A. Yes, he did.

Q. And do you agree with Mr. Tate's conclusions on the market share?

A. No.

Q. Have you prepared a slide that

demonstrates or describes your disagreement with Mr. Tate?

A. Yes, that's the next slide.

Q. And so can you briefly tell us the high level of your disagreement and then I will go through those one by one?

A. Sure. This chart shows some of the points put forward by Mr. Tate and some of my responses to those points. Number one, Mr. Tate focuses on revenue share and those are flawed in the highly generic market where the prices are very different. Number two examines competition with AAD's only, yet evidence in the case that Multaq competes with a broader set of AF drugs. And number three, even if you accept his market definition, I don't find an 11 percent market share to be a strong indicator of commercial success.

Q. Okay. So let's start with Mr. Tate's focus on revenue share. And Ted, can we bring up Tate slide 10 from yesterday? And this is the chart that Mr. Tate used to discuss the revenue shares; is that right?

A. Yes.

Q. In your opinion, is Mr. Tate's chart a fair representation of Multaq's market share?

A. No, it's not.

Q. Why not?

A. Well, because as Mr. Tate testified yesterday, there's only two branded drugs out of six AAD's on the market. And so because Multaq has a significantly higher price due to patent protection from the generics, all this market share tells you is that Multaq is one of the few branded drugs with patent protection on the market. It's just not that informative of Multaq's relative use.

Q. So is it fair to say that Multaq's higher price is the reason that it enjoys higher market share in the revenues market share?

A. Yes, that's right.

Q. You also mentioned price. Yesterday Doctor Tate testified that the premium price Multaq enjoys is evidence of Multaq's commercial success. Do you recall that testimony?

A. I do.

Q. Do you agree with that?
A. No.
Q. Why not?
A. Because this is going to be true in every single situation where you have a branded drug that has patent protection compared to prices of generics. They're higher because they have patent protection and drugs without or with generic equivalents do not, so that's really the driver. Doesn't tell us that much about commercial success.
Q. All right. Now, let's move on to the next criticism you had with Mr. Tate's market share analysis and that's mainly the market that he relies on. So again, how did Mr. Tate define the relevant market for Multaq?
A. He defined the relevant market based on antiarrhythmic drugs only.
Q. And do you believe that's the appropriate description of the market in which Multaq competes?
A. No. In my opinion that's too narrow.
Q. And why do you say that?

A. Because evidence indicates competition and substitution over a broader range of drugs, not just the AAD's.

Q. And so with what other types of drugs do you believe that Multaq competes with?

A. It also competes with rhythm control -- it competes with rhythm control drugs, of course, also with rate control drugs and to some extent anticoagulants as well.

Q. And what do you base that conclusion on?

A. That's based on my review of the evidence, particularly Sanofi internal documents and third-party market research.

Q. All right. Let's look at some of those documents. Ted, can we see JTX-242? Doctor McDuff, what is this document?

A. This is a Multaq launch plan created by Sanofi prior to launch in January 2006.

Q. And if we could look at the last section on that first page, it says market size. What is Sanofi saying here?

A. Here they're evaluating the

commercial opportunity for Multaq. And they're examining the AF market. That's the atrial fibrillation market. They have evaluation for that market that they are trying to obtain. You can see in the second sentence here the antiarrhythmic class of agents is reported as a smaller segment, so in other words Sanofi is thinking about the AF market broadly and they think of the AAD's as a class or a segment of that market.

Q. If we could look at DTX-12 now. And what is this document?

A. This is an e-mail. And if you go to page 4 of this document you'll see the plan itself. This is a Multaq marketing plan. This was completed by Sanofi after product launch.

Q. And from your review of the document, that was my question, approximately what year was this created in?

A. Around 2010.

Q. And I think you said that was after Multaq was launched in the market; is that right?

A. Yes.

Q. If we could look at page 10 of this document, ends in bates number 1135. So what is this chart telling us right here?

A. This chart is an analysis of Multaq use and where Multaq business is coming from, so it shows a variety of sources or originations. Number one switches from other AAD's. Number two, there's some switching from rate control treatment. Number three, there's adding to rate control and adding to Warfarin or anticoagulants, so you can see that there's competition in Multaq's use and business actually comes from a wide range of sources, not just other AAD's.

Q. Okay. Now, let's look at one of the other documents you mentioned DTX-205. And what is this document?

A. This document is a Medgadget research report. They're a third-party market research firm.

Q. What is this report relating to?

A. It relates to the atrial fibrillation market.

Q. And if we could look at page 3 of

this document. The second full paragraph where it says all sectors, call that out. And what is Medgadget saying about the AF market here?

A. Well, here they are confirming what we see internally at Sanofi, so they are referring to all sectors of the AF market have been historically saturated with generics. And this confirms the notion that there's a commercial opportunity in the broader AF market and there are segments that people think about, obviously the rate control, the rhythm control and anticoagulants.

Q. So taking the documents we see together, what does this tell you about the Multaq, in which market it competes?

A. It indicates a broader notion of competition and market opportunity than just the AAD's.

Q. In addition to these documents have you heard any testimony in the course of this trial that further confirms that for you?

A. Yes. This is also consistent with the deposition testimony of Mr. Fritchman that

we heard this morning, as well as testimony from Doctor Zusman.

Q. All right.

MS. CLAYTON: And Your Honor, for the record, Defendants would offer JTX-242, DTX-12 and DTX-205.

MR. ROTHMAN: No objection.

THE COURT: All right. They are admitted without objection.

BY MS. CLAYTON:

Q. Did you prepare a slide demonstrating your calculation of the market share based on prescriptions, using the various markets that we've just discussed?

A. Yes, I did.

Q. And if we could turn to the next slide, which is slide 10.

MR. ROTHMAN: Your Honor, we have an objection to an exhibit that's nested throughout this demonstrative. You can see this demonstrative refers to attachments B13 and B14, which are DTX-290 and 291. Those refer to an exhibit DTX-294A, 295A that we believe is

objectionable.

THE COURT: And it's objectionable because?

MR. ROTHMAN: Because the witness -- the document itself is a collection of IMS data. The document wasn't produced to us in fact discovery, so we didn't have the opportunity during fact discovery to figure out what the actual IMS data was. When we were presented with the IMS date in his expert report and we asked him what that collection was, he did not know. He said he received that information from counsel -- counsel or the client. He was not sure which had procured it from IMS, he wasn't familiar with what the communication was made from counsel or the client to obtain that information. And when I asked him why there were certain products on the list and not on the list, he was not able to tell me, because he did not know what request was made that arrived at the document. Lack of foundation.

THE COURT: So that's your objection, lack of foundation?

MR. ROTHMAN: Right.

THE COURT: All right. Why don't you ask some questions about that.

MS. CLAYTON: I can establish the foundation of those documents, Your Honor. I would just like to say I think that was an incorrect characterization of Doctor McDuff's testimony in his deposition.

May I approach the witness with these two documents, Your Honor?

THE COURT: Yeah. So what he said in his deposition doesn't really matter. What he says right now is what matters, okay?

MS. CLAYTON: Okay.

BY MS. CLAYTON:

Q. Doctor McDuff, you've been handed two documents which are DTX-294 and 295. What are those documents?

A. These are attachments C2 and C3 to my expert report. They provide the raw underlying IMS health data that I used for the calculation of the market shares on the slide that's up on the screen.

Q. And how did you go about obtaining this IMS data?

A. In order to obtain the IMS health data I had to request of counsel to get a broader set of IMS health data. The IMS health data that was provided by Mr. Tate was limited to AAD's only and the evidence I reviewed indicated a broader market definition, so I needed more data in order to make that market share calculation. So I requested data from IMS Health on the National Prescriptions Audit. That's related to attachment C2 and the National Disease and Therapeutic Index, the NDTI data. That's on attachment C3. I requested information on drugs that were used for atrial fibrillation.

Q. And you referred to C2 and C3. Which trial exhibit numbers do those documents have on the front?

A. DTX-294, that's for attachment C2. And DTX-295, that's for attachment C3.

Q. And what exactly -- what type of IMS data did you request from counsel in terms of the actual drug markets you were looking for?

A. I requested information from the National Prescriptions Audit because I wanted to perform a prescription share. In addition, I requested information from the National Disease and Therapeutic Index. That provides diagnosis codes, so it allows you to factor the market shares for atrial fibrillation use only. In other words, these market shares or limited to just use for atrial fibrillation. Where an anticoagulant, for example, that has a lot of non-atrial fibrillation use, the NDTI data allows you to factor that out in the calculation.

Q. And what is your understanding of how counsel obtained the IMS data for you?

A. My understanding is that they obtained it from one of the Defendants in the case.

Q. And is it your understanding that pharmaceutical companies commonly have subscriptions to this type of data?

A. Yes, it's very common.

Q. So once you received the data, did

you review it?

A. Yes.

Q. Do you frequently receive this type of IMS data in other cases?

A. Yes, all the time.

Q. How often do you think you review IMS data?

A. I've used it in at least 15 cases.

Q. Okay. And so when you reviewed the data, did the data comport with previous data that you had seen from IMS?

A. Yes, absolutely.

Q. Did it appear to be the data that you had requested from IMS?

A. Yes.

Q. In your opinion, is there -- is it the data that you had requested?

A. Yes.

MS. CLAYTON: Your Honor, we would offer these two exhibits into evidence.

THE COURT: All right. I'll allow it on that basis and you, Mr. Rothman, can address it on cross-examination.

MR. ROTHMAN: Great. Thank you,

Your Honor.

BY MS. CLAYTON:

Q. So if we could bring back up slide 10. And it's already up there. We had started to discuss the relevant markets that you have outlined here. What is the first one you have here that says atrial fibrillation?

A. This includes all atrial fibrillation use of rate control drugs, rhythm control drugs and anticoagulants.

Q. And why did you list that as a relevant market?

A. Well, this is relevant because of the broader nature of competition. They are all trying to treat atrial fibrillation. There's different methods to do so, but they all end up with the same objective or the same end result.

Q. Okay. And if we use the broader atrial fibrillation market, what was Multaq's peak share in 2015?

A. It's peak share as of several years ago, around 2011, was 2.4 percent and as of last year it has declined to 1.4 percent.

Q. And for the atrial fibrillation

market, which data between DTX-294 and 295 did you rely on?

A. It's a combination of both. It's based on the number of prescriptions having been factored for atrial fibrillation use only.

Q. Okay.

THE COURT: So Doctor McDuff, if somebody happens to prescribe Warfarin and it was described as being because they of atrial fibrillation, that would be part of the market that you would say Multaq was -- that you get this 2 or 1 percent from?

THE WITNESS: Yes, correct. If it were prescribed for something else that had a different diagnosis code, it would not be in this calculation.

BY MS. CLAYTON:

Q. And if we look at this second row here, the rate control and rhythm control, what market does that include?

A. That's limited to just the rate control drugs and just the rhythm control drugs.

Q. And why did you also list this here?

A. Because I think there's at least competition with the rate control drugs. And so in this relevant market, it relates to just treatment of those two classes.

Q. Okay. And what was Multaq's peak share in this market in their 2015 share?

A. The peak share was 4.3 percent and its declined to 2.7 percent as of last year.

Q. And again, what data did you use to reach these percentages?

A. These are the same IMS health data we've been discussing, DTX-294 and DTX-295.

Q. Okay. And finally, the third row you have rhythm control only (Tate Report). What market is that?

A. This is limited to the AAD's only as presented by Mr. Tate.

Q. And the peak share of 10.8 and the 2015 share of 7.1 percent, are those the figures that Mr. Tate offered yesterday?

A. Yes.

Q. And I just want to make sure this is clear. The top of the slide says total prescriptions. So what market share calculation

are we focused on in this slide?

A. This is the prescription share.

Q. As opposed to the revenue share; is that right?

A. Correct.

THE COURT: I'm sorry, Ms. Clayton. Is this the U.S. market or the worldwide market.

THE WITNESS: This is U.S. IMS data only is for the U.S.

BY MS. CLAYTON:

Q. So in your opinion, do any of these market shares demonstrate commercial success?

A. No, not in my view.

Q. And why is that?

A. These aren't the kind of market shares that represent a new product coming on the market and capturing the commercial opportunity of that market. Even with the rhythm control only at 11 percent peak share is not that high. It's declined to only 7 percent in recent years. And with the broader market definitions, we have a market share in the low

single digits.

Q. Now, let's move on to the next topic, which is limited future opportunity. And what do you mean by that?

A. Here I'm referring to Multaq's potential to grow in the future, whether it can, you know, achieve significantly more sales in the future than it has today.

Q. And what information did you review in determining Multaq's future opportunity?

A. I reviewed evaluations from third parties studying the market. I reviewed information from the FDA.

Q. All right. And based on your review, do you believe Multaq has a strong opportunity to make higher sales in the future?

A. No.

Q. A why not?

A. We can see one example here on the next slide.

Q. Actually I think it's -- could you bring up DTX-184, Ted. And what is this document?

A. This document is an FDA safety announcement related to the risk of death and serious cardiovascular adverse events.

Q. And if we could look at the first full paragraph in your safety announcement. What is that saying?

A. This is saying that FDA has completed a safety review of Multaq and it has shown significant risk including death and serious cardiovascular events. And this is a warning that the FDA issues for prescribers of Multaq.

Q. And whether when was this issued? What's the date?

A. In 2011.

Q. And how does this influence your opinion on Multaq's future opportunity?

A. This is the kind of safety warning that you expect to limit growth of future sales going forward.

Q. If we could look at another document, DTX-195. What is this document?

A. This is a document from a third-party market research firm relating to the

top ten drug launch disasters.

Q. Okay. And if we could turn to the second page, do you see Multaq about half way down that list?

A. Yes, I do.

Q. So what is this article saying about Multaq?

A. Well, as the title suggests, it's evaluating the top 10 drug launch disasters around this time period. So it identified Multaq because of this warning and this increased risk of death and cardiovascular event as a failed drug launch or an unsuccessful drug launch.

Q. All right. And if we could turn to DTX-199 and pull that up. What is this document?

A. This is a second third-party market research report from Global Data.

Q. And who is Global Data?

A. They are a firm that provides third-party market research in the pharmaceutical industry.

Q. And what is this report about?

A. This is about atrial fibrillation.

Q. All right. If we could look at page 7 of this document. There on the left column about a third of the way down there is a -- yeah, right there, there's a sentence starting with subsequently. And what is this sentence telling us?

A. This describes Sanofi's aim to develop an effective and safe alternative to amiodarone, but was identifying the increased risk of death and cardiovascular events that was identified in the FDA announcement. So in other words, what we expect to see is also being confirmed by parties that perform market analysis and identification of future opportunity.

Q. And taking the three documents that we've just seen together, what does this tell you about Multaq's future opportunity?

A. Well in total that it's limited. We don't expect Multaq sales to grow substantially from here.

Q. Okay.

MS. CLAYTON: And Your Honor, we

would offer DTX-184 and 195 and 199 into evidence.

MR. ROTHMAN: No objection.

THE COURT: All right. Admitted without objection.

BY MS. CLAYTON:

Q. And how does Multaq's limited future opportunity influence your opinions on commercial success?

A. Well, it's another factor that indicates that Multaq not only has not been successful through present day, it's also unlikely to become a commercial success in the future.

Q. Okay. So let's turn next to your fourth factor, no economic profitability. And first, what is economic profitability?

A. Economic profitability is a determination that weighs the benefits in terms of sales and profits that occur many years down the line with the cost of commercialization which is significant in pharmaceuticals, to see whether a product or whether Multaq has achieved an economic profit.

Q. And is economic profitability the same as accounting profit?

A. No, it's different. Accounting profits usually refer to profits or losses in a particular calendar year, so how much did a drug earn in 2015, for example. Economic profit refers to was there an economic profit over a long period of time accounting for all of the costs and all of the profits that were earned.

Q. And why are economic profits relevant to the analysis of commercial success?

A. Economic profits really get at the core of what commercial success is all about. We're trying to answer the question, were there economic incentives for the market to bring the product sooner. And if there's an economic profit opportunity, then it's, you know, a positive factor on that inference.

Q. And have you created a slide that shows what goes into an economic profitability analysis?

A. I have, yes.

Q. And if we could look at slide 13,

please. You have some bullet points here, so let's go through them one by one. First you have that the analysis includes or evaluates the incentive to develop a product. What do you mean by that?

A. Well, there I'm referring to the purpose of the economic profit analysis, we're trying to evaluate whether based on the objective sales and profits we observe, there would have been an economic incentive to bring this product to market.

Q. And the second primary bullet point is compares sales and profits to commercialization costs. What do you mean by that?

A. There I'm referring to all the economic costs that go into drug development and drug commercialization. So number one, cost of clinical trials, we know that cost of clinical trials are very expensive, hundreds of millions of dollars and they occur over a very long period of time. Those are out of pocket expenses. Second there's the opportunity costs of capital. When drugs put up hundreds of

millions of dollars over a decade or more, you have to get a return on the investment, so that return is a real economic cost. And third, there's a risk of failure and uncertainty. So sometimes pharmaceutical companies invest in research and development that ultimately doesn't pan out into an FDA approved product, so if the sales and profits are going to compensate firms for that risk or encourage them to bring the product to market sooner, it's another economic cost that needs to be taken into account.

Q. All right. And finally, you have here highlighted, are the expected profits worth the risk? What do you mean by that?

A. That's really the result of the economic profit analysis. You're trying to weigh these cost of commercialization against sales and profits that don't occur for 10 or 15 years and determine whether -- you know, which one is larger.

Q. And on this slide you also have two papers listed. Why did you include those papers in this slide?

A. These papers are two of a series

of peer-reviewed publications in the economic literature that studies this question of cost of drug development. There's probably a dozen papers or more on this topic over the years. These are two of the core papers and two of the most widely cited papers on the topic.

Q. And the most recent one, is that the 2016 one?

A. Yes, this is DiMasi, et al., 2016, in the Journal of Health Economics.

MS. CLAYTON: Your Honor, that's JTX-228 and we would offer that in evidence at this time.

MR. ROTHMAN: No objection.

THE COURT: All right. That's admitted without objection.

BY MS. CLAYTON:

Q. Does the DiMasi 2016 paper discuss how expensive it is to bring a new drug to market?

A. It does.

Q. And what do they estimate that expense to be?

A. Well, the literature has long

agreed for decades that it costs more than a billion dollars to bring a new drug to market. The most recent estimate by DiMasi 2016 and others are that it's in excess of two billion.

Q. Based on the DiMasi paper, did you do a calculation about the estimated cost for bringing Multaq to market?

A. Yes.

Q. And have you prepared a slide that shows how you used the DiMasi paper in your assessment of Multaq?

A. Yes, I have.

Q. If you could bring up the next slide. This is slide 14. You have two columns or three columns. You have description, then the DiMasi paper and Multaq. So can you describe for us here how you use the DiMasi paper to arrive at these entires for Multaq over here?

A. Yes. The exercise here is to determine whether the facts and circumstances of Multaq are similar to the DiMasi 2016 study. And you can see that in this situation they are quite similar. In terms of the product type,

DiMasi and its co-authors studying new chemical entities. Multaq is of course a new chemical entity. The drugs studied in DiMasi 2016 received FDA marketing approval from 2005 to 2013. Multaq, in 2009, falls squarely in that range. There was initial clinical testing for the drugs in the DiMasi paper from 1995 to 2007. Multaq, again, is right in the middle of that range in 2001. The average time to approval is 8.1 years in the published literature. Multaq is 7.7 years, very similar. And the time of clinical testing from the published literature is 7.9 years, compared to Multaq as 12.4 years since clinical testing has been substantially ongoing even after approval.

Q. And in addition to the information from DiMasi, did you use other information from Sanofi to a arrive at the cost of commercialization?

A. Yes, I did. So part of the inquiry here is to determine the actual facts related to Multaq, when it received marketing approval, when the clinical trials took place. And I used Sanofi information in order to do

that.

Q. Okay. And what did you arrive at for the cost of commercialization for Multaq?

A. The DiMasi paper provides an estimate of 2.59 billion for an average drug. Based on when Multaq came to market, I've estimated 2.39 billion for Multaq.

Q. All right. And are you aware of any factors that would indicate a potentially even higher commercialization cost for Multaq?

A. Yes, because the clinical trials for Multaq have been substantial, they've been more than the average drug, if anything, I'd expect this to be higher.

Q. So in your opinion is this a conservative estimation of the cost of commercialization of Multaq?

A. Yes.

Q. Now, is this the same cost of commercialization that was in your expert report?

A. It's very close. It's slightly different because the DiMasi 2016 paper only

came out in March of this year after my expert report. I had estimated what development costs would have been for a drug released around this time and had estimated something actually within $20 million of what the DiMasi estimate ultimately turned out to be.

Q. Using the cost of commercialization here, did you perform an economic profitability calculation for Multaq?

A. Yes, that's on the next slide.

Q. And that is slide 15 for the record?

MR. ROTHMAN: Your Honor, we have an objection to this exhibit as well. This demonstrative refers to DTX-11, which is a document that internally relies on a Sanofi document that this witness was not able to lay the proper foundation for in his testimony.

MS. CLAYTON: And again, I can lay that proper foundation now, Your Honor.

THE COURT: All right. Why don't you do that.

BY MS. CLAYTON:

Q. If you could turn to JTX-238 in

your binder. And Ted, if you could bring that up on the screen as well. Did you use this document in performing -- in some of the calculations that we see on slide 15?

A. Yes, I did.

Q. And what is this document?

A. This document provides expected sales and costs for Multaq.

Q. And who generated this document?

A. This was provided by Sanofi. I believe they generated it.

Q. Okay. And how did you go about obtaining this document?

A. I obtained this document by searching for electronic production. I'm unaware of Sanofi providing official profit and loss calculations for Multaq retrospectively, so this was the best information on profits that I could find.

Q. So you said that you searched electronic documents. Was that Sanofi's entire production database?

A. Yes.

Q. And was this the -- in your

opinion, the most accurate estimation of the costs that you could find?

A. It is, combined with information from other documents as well.

Q. Okay. And upon a review of this document, what year do you believe this document was created?

A. I believe it was created in the late 2000's, likely around 2009. You can see in the assumptions and comments here that 2009 to 2011 is based on a budget for 2009 and long-range plan for 2010 and 2011. Those commonly refer to the current year or the next year as well as planning into the future.

Q. What about this document makes you think it's a Sanofi document?

A. Well, Sanofi of course is the company selling Multaq at the time. It comes from their production and this is exactly the kind of planning and profit calculation I expect them to perform.

Q. Now, at your deposition, I don't think you gave a specific year as to when you thought this was created; is that right?

A. That's correct. There was some back and forth at deposition on this.

Q. And based on a further review of the document, I think you said you believe it's created in 2009; is that right?

A. Yeah, correct. When the document was first provided to me at deposition, I didn't see a date on it immediately. There's no date in the title, no date in a footnote, so I originally didn't see that, but as we were doing the question and answer, I noticed these assumptions in comments and was able to provide essentially the same answer that I did here at trial.

MS. CLAYTON: Your Honor, we would offer JTX-238 into evidence and believe that he established a sufficient foundation to use this for his calculations.

THE COURT: Is it JTX-238 that the objection is to?

MR. ROTHMAN: Yes, that's correct, Your Honor.

THE COURT: All right. Well, I'm going to admit it and you may proceed.

MS. CLAYTON: Thank you, Your Honor.

BY MS. CLAYTON:

Q. If we can go back to slide 15 and there's a lot of information on this slide, so I want to break it down one by one. And I see that first you have highlighted 2015. Why do you have 2015 highlighted here?

A. That represents a calculation of sales and profits through present day or through the end of last year. That represents the, in other words, the objective sales in evidence that have already occurred.

Q. Okay. And in 2015, what did you calculate to be the present value cumulative?

A. Negative 1.78 billion.

Q. Okay. And how did you -- from this chart, what numbers did you use to arrive at that calculation?

A. Well, you can see the three columns here. The first column are the actual profits and losses of Multaq over time. So those are based on revenue information from the 20F's as well as the cost information we

reviewed in the previous document as well as other documents. The second column is the present value in 2009 dollars of those future cash flows. It's standard practice in an analysis like this to discount future sales for risk and uncertainty, so I've done so here, discounted back to 2009. You can see the top of that column, that's the R & D figure for the commercialization costs from the previous slide, that's what we're trying to weigh the profits against. And in the third column is the present value of the profits and losses on a cumulative basis. So we start with the negative amount or the investment into the product and we're trying to ask the question, do the profits ultimately become positive over time.

Q. Okay. And so the profit and lost, we start up here with -- or R & D, the cost of commercialization as we saw on your previous slide; is that right?

A. Yes.

Q. And then what other information did you use to arrive at that 253 number there?

A. That's based on the revenue

information reported by Sanofi as well as the cost information from internal documents.

Q. All right. And if you could turn your binder to DTX-1, DTX-3, DTX-8, JTX-238 that we looked at before, JTX-238 and JTX-240, are those the calculations and documents that you used in arriving at this 253 number in the profit and loss column?

A. Yes.

MS. CLAYTON: Your Honor, some of those have already been admitted. We'd offer DTX-8, JTX-239 and JTX-240 into evidence.

MR. ROTHMAN: Our only objection is to the extent they rely on the document previously objected to, but you've overruled that objection.

THE COURT: All right. So noted and otherwise admitted without objection.

BY MS. CLAYTON:

Q. Now, let's focus again on the present value in 2009 dollars, the 114 number that you list there. Now, I think you mentioned that you used a discount in arriving at the 114 number; is that right?

A. Yes, I used an 11 percent discount for the cost of capital in the pharmaceuticals industry.

Q. So you start again with the cost of commercialization number and use a discount to arrive at the 114. Any other information that you used to arrive at that 114 number?

A. Well, this is a calculation using that discount rate of 11 percent, that does take into account the opportunity cost of the capital. It does not take into account potential risk that those sales might not occur. For example, if there's generic entry, sales into the future, at least from the perspective of 2009 may not occur, so that's the additional risk that could push the discount rate even higher to make the economic profits even lower.

Q. So for your number here, though, you didn't take that additional risk into account, right?

A. Correct, I just used the opportunity costs of capital.

Q. And so in your opinion, is this a conservative number that you used here?

A. It is.

Q. And quickly, if you could look at DTX-8, DTX-11, DTX-296, JTX-144 and JTX-145 in your binders, are those the calculations and underlying documents that you used to come up with the 114 number in this chart?

A. Yes.

MS. CLAYTON: And again, only one isn't in evidence and Your Honor, we'd offer DTX-11 into evidence.

MR. ROTHMAN: To the extent that doesn't rely on DTX-238, we don't have an objection.

THE COURT: All right. It's admitted without objection other than the caveat.

BY MS. CLAYTON:

Q. So for the 2015 calculation, again, what is the present value cumulative?

A. Negative $1.78 billion.

Q. And what does that tell you about the commercial success of Multaq?

A. Through present day Multaq has not recouped its commercialization costs.

Q. Okay. And you also have highlighted on here 2023. What does that line represent?

A. That represents the projections put forward by Mr. Tate yesterday and the result in economic profit if those future sales are included.

Q. Is there a difference between the number you arrived at here and the number Mr. Tate arrived at?

A. There's a difference in the economic profit, because we have a dispute over what the commercialization costs are, but there's no difference in the profit and loss figures that we use. We use the same revenue, the same projections and the same cost allocation.

Q. Right. And if you look at PTX-286 in your binder, is that the calculation that Mr. Tate used for those numbers? It's up on the screen, if that's easier.

A. Yes, it is, as well as the next page of this exhibit.

Q. And is that -- and you based your

numbers from 2016 to 2023 in the previous chart on these calculations done by Mr. Tate?

A. Yes. And if you show the next page of this exhibit, I believe you'll see all the same figures there. So here you can see the same figures under nominal worldwide profits and you can see the same figures in the present value of worldwide profits in the column all the way on the right.

Q. And if we could go back to slide 15. Projecting out to 2023 as Mr. Tate did and using his underlying analysis, what did you determine the present value cumulative of Multaq to be in that year?

A. Negative 1.15 billion.

Q. And what does that tell you about the commercial success of Multaq?

A. Not only has it not been a commercial success to date, it's unlikely to recoup its investment and become a commercial success.

Q. Have you also determined whether Multaq would be profitable when the '167 Patent expires in 2029?

A. I have.

Q. And what was your determination in that regard?

A. Even pulling the calculations out through 2029, it still does not achieve an economic profit.

Q. All right. In this chart your profit and loss calculations assume certain projected levels of annual costs; is that right?

A. Yes.

Q. Is that the Sanofi document that we discussed in a little more detail earlier?

A. In part, yes.

Q. And have you considered whether Multaq would be profitable assuming lower annual costs for Multaq?

A. I have. There was some discussion at my deposition on potential alternative parameters for costs. I've run the numbers both ways and no matter what set of parameters you use, there's no economic profit here.

Q. So in sum, what is your opinion regarding Multaq's economic profitability?

A. That it has not earned an economic

profit to date and it's unlikely to ever earn an economic profit.

Q. And how does that influence your opinions on commercial success?

A. It indicates that Multaq is not a commercial success and will not become a commercial success in the future.

Q. Okay. Now, we've briefly discussed Mr. Tate's opinions on economic profitability. You were here for his testimony on that yesterday?

A. I was.

Q. And do you agree with his opinion on economic profitability?

A. No.

Q. And have you created a demonstrative that shows the differences in your calculation versus Mr. Tate's calculation?

A. Yes, I have.

Q. And if we could bring that up, it's slide 16. So could you describe here what you're showing in this slide?

A. Yes. This slide shows a comparison of the calculations put forward by

Mr. Tate and the calculations that I've put forward. There are actually quite a lot of similarities between the two calculations. We both use the same academic literature to get commercialization costs. And we have the same adjustments to make them specific for Multaq. We have the same profits and losses, the same projections. There's really only one difference which is that he does not include the risk of failure in his calculations and I do.

Q. And in your opinion is it appropriate to exclude the risk of failure as Mr. Tate did?

A. No.

Q. And why not?

A. Excluding the risk of failure excludes a real economic cost that's based by pharmaceutical companies. When a pharmaceutical company is thinking about whether a product has a sufficient market opportunity to want them to bring it to market, they think about the fact that they might invest hundreds of millions of dollars in development or clinical trials that ultimately might not receive any profit at all.

So it's a real risk that's evaluated. It's a cost that's taken into account in all the academic literature on this topic and it's a costs that's inappropriately removed by Mr. Tate.

Q. And so what number did Mr. Tate arrive at and what number did you arrive at for economic profitability?

A. Well, for commercialization costs, this is the difference. You can see the 1.04 billion in the commercialization costs for Mr. Tate. That takes out the risk of failure. And the 2.39 billion in my calculations. And one point that be may be helpful to clarify as well, is that Mr. Tate described this as me assigning the costs of failed drugs to these commercialization costs. That's the wrong way to think about it. That's what they do in the academic literature in order to determine the risk of failure. You want to determine how likely is it and what are the costs of persuing success as well as drugs that do not receive approval. But the purpose is to get the risk of failure and that's a real economic cost.

Q. And the actual profit that you calculated and Mr. Tate calculated, what were each of those numbers?

A. Well, through 2015, both calculations show no economic profit to date. Mr. Tate is at negative .54 billion and mine is at negative 1.78 billion. And when you project through 2023, in other words seven years from now, Mr. Tate's calculations barely become positive at just $200 million. And mine are still quite significantly negative at minus 1.15 billion.

Q. So Doctor McDuff, we've just gone through the economic profitability of Multaq. We've already discussed the factor related to the sales of Multaq, it's market share and it's future opportunity. Based on all of these factors that we have just discussed, what do you conclude about the commercial success of Multaq?

A. Well, based on the economic profit analysis, it indicates Multaq has not been a commercial success and is unlikely to become a commercial success.

Q. Yesterday I believe Mr. Tate

testified that the existence of ANDA filers is evidence of commercial success. Do you recall that testimony?

A. I do.

Q. And do you agree with that?

A. No, because there's a fundamental difference in the commercialization costs between branded drug companies and generic drug companies. Just because a generic drug company is interested in filing an ANDA application and providing a generic product doesn't mean that a branded pharmaceutical company would have the same economic incentives to bring that product to market from scratch. So if you're thinking about commercial success as incentives to bring the product to market sooner, the evidence of generic filers is not -- does not show commercial success of the product.

Q. All right. Now, let's switch gears a little bit and talk about your fifth point, which is blocking patent and exclusivity. What is a blocking patent?

A. A blocking patent is a term that refers to a patent that blocks or prevents a

competitor from commercializing the product.

Q. And exclusivity, what do you mean by that here?

A. That refers to regulatory exclusivity granted by the FDA.

Q. Okay. And to discuss both of these, let's look at JTX-227. What is this document?

A. This document is the FDA Orange Book for Multaq.

Q. Okay. And what is -- if we could, Ted, pull up the charts that are underneath that heading. What is this chart showing?

A. This chart shows the patents that are listed in the FDA Orange Book for Multaq.

Q. Okay. And in addition to the '167 Patent, how many other patents are listed in the Orange Book?

A. Five other patents.

Q. And the first one listed there is the '510 Patent. Do you see that?

A. Yes.

Q. What is the understanding of the subject matter of that patent?

A. That patent provides the Dronedarone compound.

Q. What people refer to as a compound patent?

A. Yes.

Q. And is it your understanding that compound patents are frequently referred to as blocking patents?

A. Yes, that's generally accepted.

Q. And what is your basis for that understanding?

A. Based on my professional experience and work on this kind of technology.

Q. Does the presence of a blocking patent change the way you think about commercial success?

A. Yes. What a blocking patent does is even if there is a commercial opportunity or even if a company might have been interested in bringing a product to market, a blocking patent limits the economic relevance of that commercial opportunity because companies would have been prevented from commercializing that product

sooner.

Q. Now, if we could go back to the full Orange Book for a moment and right now I just want to focus on the exclusivity section down there. What is this exclusivity section in the Orange Book telling us?

A. This refers to FDA regulatory exclusivity.

Q. And I see under the exclusivity code, it says NCE. What does that mean?

A. That is new chemical entity.

Q. So what is having new or NCE exclusivity, what does that afford Sanofi?

A. That provides that Sanofi will be the only entity selling a Dronedarone product. Also, generic ANDA filers need to wait until one year before the exclusivity period ends in order to file an ANDA application.

Q. Okay. And how does the existence of this exclusivity for Sanofi influence your analysis on commercial success?

A. It's another factor even outside of the blocking patent that limits the economic relevance of commercial success since other

entities would be prevented from commercializing a Dronedarone product.

Q. Okay. So taking both the '510 blocking patent and the NCE exclusivity together, how do these together impact your analysis of commercial success?

A. Both of those factors indicate that even if there were a commercial opportunity, the economic relevance of commercial success is not significant here.

Q. And why is that?

A. Because both of these items, the blocking patents and the exclusivity, they get in the way of this incentive to bring the product to market sooner. So it kind of cuts through even if there were a commercial opportunity what the inference can be about commercial success.

Q. So now let's go to the last topic in your primary findings, no demonstrated nexus. First, what is a nexus?

A. A nexus is a factual or economic connection between the patents in suit and sales or use of a product.

Q. And how does an analysis of nexus fit within the analysis of commercial success?

A. It's one factor that's frequently evaluated in evaluating commercial success. If commercial success is due to factors besides the claimed invention, then there are limits on what one wants to infer about the claimed invention from any commercial success.

Q. And in your understanding, did Mr. Tate offer an opinion on nexus?

A. I understand he did not.

Q. What about Doctor Reiffel, in your understanding did he offer an opinion on nexus?

A. I understand he offered an opinion that there is a nexus between sales of Multaq or use of Multaq and the '167 Patent.

Q. And in your understanding, what did he base that on?

A. That was based on his, his

clinical experience prescribing the drug.

Q. Okay. And did you find Doctor Reiffel's opinion complete and satisfactory?

A. No, not in my view.

Q. And why not?

A. Primarily because Doctor Reiffel and Plaintiffs more generally failed to analyze the other technologies or other patents that are related to Multaq, not just the '167 Patent.

Q. What is your understanding about whether or not Multaq is given only to the patients described in the '167 Patent?

A. My understanding is that it has use outside of the patient population alleged to be covered by the '167 Patent.

Q. And what effect does including these patients have in the nexus analysis?

A. Well, what it says is that because there's a group of patients that's known to be outside the '167 Patents, Plaintiffs are attributing some sales or some commercial success where there's no nexus at all.

Q. Okay. And I think you also mentioned that he ignored the other patents that

are covering Multaq; is that right?

A. Yes.

Q. If we could bring up JTX-277 again --

MS. CLAYTON: And Your Honor, before I think I failed to offer this into evidence, so I'd offer JTX-227 into evidence.

MR. ROTHMAN: No objection.

THE COURT: I'm sorry, JTX what?

MS. CLAYTON: 227.

THE COURT: Okay. All right. Admitted without objection.

BY MS. CLAYTON:

Q. And I believe earlier you said that the '510 Patent here is a compound patent, right?

A. Yes.

Q. Does the presence of the '510 Patent, which is the compound patent, effect the nexus analysis in your opinion?

A. Yes, it does. Because the compound patents are generally known to be a strong driving contributor to sales and so to ignore or to not even think about the presence

of the compound patent relevant to the contribution of the '167 Patent, falls short of demonstrating a nexus in my view.

Q. Now, we also see listed here a '493 Patent and an '800 Patent. What is your understanding of what these patents relate to?

A. I understand these to provide formulations of Multaq.

Q. Okay. And does the presence of formulation patents such as these effect the nexus analysis?

A. Yes, again these are other contributing factors or contributing technologies to Multaq and they are factors that haven't been examined by Plaintiffs at all.

Q. And I also see that there are two other patents listed here, the '215 and the '900 Patents. Do you see those?

A. Yes.

Q. And is it possible that the presence of these patents also effect the nexus analysis?

A. Yes. And they have not been analyzed by Plaintiffs.

Q. Okay. So to your knowledge have Plaintiffs provided any analysis of the nexus to the commercial sales of Multaq to any of these other patents that we just discussed?

A. No.

Q. And what does that lead you conclude about Plaintiff's nexus analysis?

A. Well, in my view, for the reasons we've discussed, Plaintiffs have not demonstrated a nexus in this case.

Q. And so before we conclude, I just want to summarize for the Court your overall opinions here on the last slide in 19. Can you just remind us of your overall opinions?

A. Yes. Number one, Multaq has not been a commercial success and is unlikely to become a commercial success in the future. Number two, there were disincentives for development in the form of blocking patents and exclusivity that limit the economic relevance of commercial success even if it exists. And third, Plaintiffs have not demonstrated a nexus between the patents in suit and sales of Multaq.

MS. CLAYTON: Your Honor, one

housekeeping matter. I failed to admit DTX-1, which is one of Mr. McDuff's underlying calculations and I would offer it at this time.

MR. ROTHMAN: We have no objection to that.

THE COURT: Okay. Admitted without objection. Actually, can we just go back before we do the cross. The slide that compares him and Mr. Tate on the --

MS. CLAYTON: Slide 16?

THE COURT: Put it up and we'll see. Yes. Doctor McDuff, the reason the commercialization costs which you say reflects the risk of failure in yours but not in Mr. Tate's and seems to be $1.3 billion worth of difference, that's because of money -- just explain to me how the risk of failure translates into dollars. Maybe you did this already once. I didn't quite get it.

THE WITNESS: The way it works, in the literature they are trying to provide the total cost of bringing a new drug to market. So if you have some projects that go forward, you incur some phase one costs, maybe some phase two

costs, you get failure. You spend that money and you never recoup that money. And sometimes you have a drug that gets all the way through to clinical trials. So if you're thinking about the total cost of bringing a new drug to market or the ex ante cost, thinking about the expected cost going forward, you have some chance of success and some chance of failure. And the data indicate that more than three quarters of drugs never get approval. And so a drug company thinking about the total economic cost, and as in the economic literature, takes this risk of failure in that calculation.

THE COURT: So if say Sanofi had developed, we'll just call it Compound Z, and done some trials or does the work with that and eventually dropped it as being a non-starter, that could go into this 2.39 billion figure?

THE WITNESS: That's not really the right way to think about it. It's not if they spent more money on other drugs that would go into this figure. It's more that when they're starting for Multaq, there's some risk that Multaq will not receive approval. So it's

unrelated to the amount that's spent on other drugs. That's just how it's calibrated in terms of getting the risk of failure.

THE COURT: So that -- so that's kind of the reason I'm asking the question, because -- and I got that you had your 2.39 billion figures come from DiMasi or whatever, but the actual -- is this kind of like an overhead cost?

THE WITNESS: Not really. It's -- the purpose is to try to get at the notion that the sales and profits need to be big enough in expectation that I might be able to get those sales and profits and I might not when I'm embarking on the commercialization process.

THE COURT: So you say ex ante. If you think about it and you've got five potential drugs you can pursue and trials and all that and you think 80 percent of drugs that we start off with fail, then what you're saying is that you need to think of one of those as returning a lot more profits than are just associated with that particular drug because you've got to cover the fact that you can't tell

which ones are going to fail and which ones are going to succeed?

THE WITNESS: Yes, that's exactly right.

MS. CLAYTON: Thank you, Your Honor. No further questions.

THE COURT: All right. Mr. Rothman.

BY MR. ROTHMAN:

Q. Good morning. Nice to see you again.

A. Good morning. Nice to see you.

Q. If you had the actual amount that Sanofi spent to develop Multaq, that would be much less than the number you're suggesting, right?

A. In terms of out of pocket expenses?

Q. Right.

A. That's correct, because the dollars themselves don't account for opportunity cost and risk of failure.

Q. The actual cost of developing Multaq is much different than the number you're

suggesting because you include the risk of failure, right?

A. I wouldn't put it that way. They are just two different measures.

Q. Okay. I just have a few questions about how we got here. Who contacted you initially about this case?

A. I believe it was Carlson and Caspers. They represent one of the Defendants that's no longer in the case.

Q. When did they contact you?

A. Sometime in the fall of last year.

Q. And you served an expert report in this case, right?

A. Yes.

Q. And you were deposed in this case by me, right?

A. I was.

Q. And Sandoz and Watson weren't at that deposition, were they?

A. I don't believe so.

Q. In fact, no one here in this room, I don't think, other than me was at that deposition, right?

A. I believe that's right.

MS. CLAYTON: Your Honor, I just object to the relevance of these questions.

THE COURT: Overruled.

BY MR. ROTHMAN:

Q. All right. You're not a medicinal chemist, right?

A. No, I'm an economist.

Q. You're not a pharmaceutical formulator?

A. No.

Q. You're not an expert in the medical field, are you?

A. In the application of economics in that area, yes, but not as a clinician.

Q. Before you worked on this case, you didn't have any experience with atrial fibrillation, right?

A. Not specifically.

Q. You didn't have any experience with Multaq?

A. No.

Q. You didn't ever do any work on antiarrhythmics, right?

A. Not before this case.

Q. And as we said, you served an expert report in this case, right?

A. Yes.

Q. And you used your best judgment at that time in arriving at the opinions in your expert report, isn't that right?

A. I certainly did my best to do so.

Q. All right. Let's -- you learned a little bit about afib treatment throughout your work in this case, right?

A. Yes.

Q. Management of afib involves three objectives, right?

A. That's my understanding.

Q. One of those is rate control?

A. Yes.

Q. Prevention of thromboembolism?

A. Yes.

Q. Correction of rhythm disturbance?

A. Yes.

Q. The rate control strategy is prescribing drugs that primarily focus on rate control?

A. It is, yes.

Q. The rhythm control strategy means prescribing a drug focused on rhythm control, right?

A. If a physician chooses to go that way, yes.

Q. And antithrombic drugs address the obstruction of blood vessels in blood clots, right?

A. Yes.

Q. Rhythm control drugs are sometimes referred to as antiarrhythmic drugs?

A. They are.

Q. Sometimes called AAD's?

A. Yes.

Q. Before I forget this one. You mentioned the words economic profitability and accounting profitability in your direct, right?

A. I did.

Q. And accounting profitability wasn't contained in your expert report anywhere, was it?

A. Well, it's inherent in the

economic profit calculation.

Q. There's no doubt that Multaq has accounting profitability, right?

A. I would say that's not clear based on the level of sales today.

Q. Billions of dollars it's made from 2009 through till 2014, you don't think that shows accounting profitability; is that your testimony?

A. I would have to look. It would be close.

Q. All right. Let's talk about the market for Multaq. If the doctor chooses to prescribe an antithrombic, you understand Multaq's not considered, right?

A. Depends at which stage you're talking about.

MR. ROTHMAN: May I approach, Your Honor?

THE COURT: Sure.

BY MR. ROTHMAN:

Q. You gave a deposition in this case, right?

A. Yes.

Q. I asked the questions, right?
A. You did.
Q. You did your best to answer the questions truthfully and accurately and completely, right?
A. Yes.
Q. Let's turn to his deposition, page 113, lines 4 to 7.
MS. CLAYTON: I'm sorry, line what?
MR. ROTHMAN: Lines 4 to 7.
BY MR. ROTHMAN:
Q. I asked you this question. If a doctor chooses an antithrombic agent, is Multaq considered. Answer, I would refer to clinicians on that. My understanding typically not.
Did I ask you that question and you give that answer?
A. You did. I think that's consistent with what I provided. It depends on what he -- when you're talking about that decision point.
Q. You know doctors don't substitute AAD's for anticoagulants, right?

A. Not in terms of being medically equivalent.

Q. And you know that AAD's are not medically equivalent to anticoagulants, right?

A. That's my understanding.

Q. And you understand that Dronedarone is not used as a rate drug, right?

A. I understand that it does have some rate control properties.

Q. Can we pull up page 237, lines 10 to 14. In your deposition I asked you, is it your understanding that Dronedarone is used as a rate drug? Answer, I would defer to a medical expert on that. Generally speaking that's not my understanding.

Did I ask you that question and did you give that answer?

A. You did. The reason why my answer is slightly different here is that I talked to Doctor Zusman about that issue this week in response to part of the issues that were coming up in trial. While it's not used as a rate drug specifically, I understand that it does have

some rate control properties.

Q. You read Doctor Zusman's reports in this case before the deposition, right?

A. I don't recall. I believe so.

Q. So you had the benefit of his knowledge when you gave the answer in your deposition, isn't that right?

A. Certainly gave the best answer that I could. But as I indicated, I clarified this week after discussions with him.

Q. You understand Doctor Zusman doesn't prescribe Multaq when a patient has a blood pressure over 120 solely, right?

A. He may, I'm not sure.

Q. How about if he has a heart rate above 120?

A. He may, I'm not sure.

Q. Were you in court on Monday when he actually provided his testimony to the Court?

A. I was not.

Q. Did you read his transcript from when he testified in court?

A. No, but I discussed some of his testimony with him personally.

Q. And so if you found out that he testified in court that if a patient walked in with a blood pressure -- with a heart rate of over 120 he would not prescribe Multaq without a rate drug, would that surprise you?

A. No, that's what I'm trying to convey. Multaq is not used, to my understanding, as a rate drug exclusively. It does have some rate control properties.

Q. Okay. At that time you couldn't think of any instance in which you've seen Dronedarone used as a rate drug; isn't that right?

A. That's right. Not from a clinical perspective.

Q. Let's talk a little bit about Multaq's properties, compared to the other AAD's in the market, okay? Multaq's is not equivalent to the other AAD's in the market; isn't that right?

A. That's correct.

Q. And despite the generic competition, Multaq is prescribed because each patient is a unique circumstance that physicians

make a determination for, right?

A. I think that's fair.

Q. And one of the contributing factors deriving Multaq sales are the differences in properties between Multaq and the other AAD's, right?

A. Yes.

Q. You compare -- so we're going to talk about benchmarks now. You talked about bench marks a little bit in your direct, right?

A. We did.

Q. You compare Multaq sales to Lipitor, right?

A. I did as one cardiovascular drug comparison. Not in my testimony, but in my report.

Q. Right. That was your best professional judgment was to include a comparison between Multaq and Lipitor as part of your analysis for commercial success?

A. Well, it was one of many factors I considered, yes.

Q. You think comparing Multaq to Lipitor is a good indication as to whether

Multaq is commercially successful, right?

A. Not by itself I wouldn't rely on that, but I think it helps put these sales into context. People often get confused that $350 million sounds like a lot in the abstract sense and the purpose of that exercise is to put those dollars into context in the industry and cardiovascular drugs specifically.

Q. Lipitor is used to treat cholesterol, isn't it?

A. Yes.

Q. Lipitor has a larger patient population than Multaq does, right?

A. It does.

Q. Lipitor has a larger commercial opportunity than Multaq, right?

A. Absolutely.

Q. And Lipitor's sales are due in part of the patient population that is available to be treated by Lipitor, right?

A. Absolutely, that's partly the point.

Q. And Multaq doesn't have that same opportunity, does it?

A. No, it doesn't.

Q. Now, let's turn to Crestor. That's a second drug you compared Multaq to, right?

A. As one of many comparisons, yes.

Q. Crestor is also used to treat cholesterol, right?

A. Yes.

Q. Has the same patient population as Lipitor?

A. Generally, yes.

Q. Same advantages over -- same advantages over Multaq, right?

A. Advantages over Multaq?

Q. As far as the commercial opportunity.

A. Yes, I think it's a larger commercial opportunity. The commercial opportunity for Multaq as we've seen is much more limited.

Q. All right. Now, let's turn to Diovan. You also compared Multaq to Diovan, right?

A. As one of many comparisons, yes.

Q. All right. And when I deposed you, you didn't even know what Diovan treated, right?

A. Not specifically, yes. It's a cardiovascular drug.

Q. You didn't even care, right?

A. I just couldn't remember at the time.

Q. But you didn't care what it treated. As far as your analysis, that didn't matter?

A. I wouldn't put it that way.

Q. Can you pull up page 155, lines 13 to 22. Question, but Diovan, you don't know what it does? Answer, I don't remember sitting here. Question, you just know that it's a cardiovascular drug; is that right? Answer, yes. Question, does it matter what it treats for your analysis? Answer, not particularly.

I asked you those questions and you gave that answer, right?

A. I did, yes.

Q. All right. You compared Multaq to oral anticoagulants, right?

A. As one of many comparisons to put it into context, yes.

Q. And the patient population for oral anticoagulants is much different than afib patients, right?

A. Well, they are not identical.

Q. They are much different, right?

A. That's a different patient population, yes.

Q. You also compare Multaq to calcium channel blockers, right?

A. As one comparison, yes.

Q. And they have a different patient population than Multaq, right?

A. They do.

Q. In your direct testimony you identified what you believe is the relevant market for Multaq, right?

A. Yes.

Q. You identified I think several of them, didn't you? There was about three of them, I think?

A. Yes.

Q. Okay. So if you keep any of

those -- I recognize there's a dispute between the parties as to what the relevant market is, but for purposes of this question, you can pick any of those three markets, okay? Do you have them in your head?

A. I do.

Q. Okay. So now if you go to slide 7 of your demonstrative, this is what you have entitled Comparisons to the Pharma Industry. You've got the first as 1st Decile, right?

A. Yes.

Q. Do all the drugs in the 1st Decile fall into any of your three markets?

A. All of them, no. Some of them would, some of them would not.

Q. Okay. And if you look at the 2nd Decile, do all the products in the 2nd Decile fall into any of your three relevant markets?

A. Not all of them. Some of them yes, some of them no.

Q. And for that mean line, do all of those products fall into any of your three relevant markets?

A. All of them? Of course not.

Q. Okay. All right. Let's turn now to your cost of commercialization analysis, okay? You spent a fair amount of time with that on direct so we'll see what we can do with it. At it's most basic level, your analysis asks the question whether you make more money than it costs to make, right?

A. I think that's fair.

Q. And you endeavor to calculate how much profit Multaq made, right?

A. Yes.

Q. And then you calculated the cost of developing Multaq, right?

A. Yes.

Q. In your report, you rely on case law to support your understanding of what commercial success is, right?

A. It's one of a number of factors that develops my understanding.

Q. And none of the cases you rely on discuss profitability, do they?

A. I would disagree with that. Certainly not in concept.

Q. Okay. We can address that in post

trial briefing. Let's discuss where you got your numbers for the costs of development of Multaq, okay?

A. Okay.

Q. For the costs of developing Multaq, you didn't use any internal Sanofi data, right?

A. No. Unfortunately Sanofi did not provide that information.

Q. Okay. You don't actually know how much Sanofi spent on research and development for Multaq, do you?

A. Not to the dollar, yet the estimates I've provided are reasonable and reliable and they were utilized by Mr. Tate as well.

Q. And those estimates you rely on are based on references, right?

A. They are based on peer-reviewed academic literature, yes.

Q. And you don't believe that the data you rely upon from those references uses Multaq data at all, right?

A. Not specifically, yet part of the

exercise is to connect the estimates from that paper to specific facts and circumstances of Multaq, which is what I've done here.

Q. Okay. And so the estimation you rely upon from those articles as to the costs of developing a product, as we've discussed for a while, includes the costs of development failures, right?

A. It includes the economic risk of failure.

Q. And in your analysis, you didn't provide an estimate as to what the costs of development would be if you did not include those development failures, did you?

A. No, because I don't think it's appropriate to exclude them. I did on my direct testimony provide a comparison of Mr. Tate and myself, and that is the difference.

Q. But Mr. Tate didn't do his own analysis independently, did he?

A. No. In his initial report that was one of my critiques, he didn't examine profits at all which I think is completely inappropriate in examining commercial success.

Q. He just took your analysis and pointed out what was wrong with it, isn't that right?

A. In his view and as I mentioned he didn't point out many things that were wrong with it, only the risk of failure.

Q. He pointed out a couple things and we're going to get to the other ones soon, but it's not fair to say that this is his analysis with regard to profitability, he didn't independently find those articles and come up with this analysis, he merely took yours and was poking holes in it, isn't that right?

A. I would let him describe it. You could describe it that way.

Q. Okay. So when we look at the slides and you compare the two and you say oh, look, they are almost identical, that's because he just took your analysis and was picking the two or three things he was taking issue with, it's not that he as an economics expert is approaching the Court saying I think this is the analysis and this is the way I would do it.

That's not the way his opinion reads, right?

A. Well, I think that's right. But this is what we do as economic experts all the time.

Q. That answers my question. Thank you very much.

A. Is we provide the primary critiques. He pointed out the primary things he thought were wrong and there was just two items.

Q. And you compare your profit number to the cost number to reach your conclusion, right?

A. Yes.

Q. And you didn't create this analysis, did you, on your own, you rely on publications that were out there before you, right?

A. I'm not sure I understand.

Q. You weren't the first one to come up with this cost of commercialization analysis, are you?

A. No, it's widely available in a number of papers.

Q. Right. You rely on the publicly

available references that teach you how to do the analysis, right?

A. Yes, absolutely.

Q. And one of the references you rely upon is Grabowski from 2002, right?

A. It is.

Q. Okay. When you did your calculation for the cost of development, you included the entire cost of development, right?

A. Yes, as I would think of it.

Q. You didn't just take the first five years, did you?

A. No.

Q. And in fact, your cost of development is really just an estimate, right?

A. It's a reliable estimate.

Q. And it's an estimate because you don't have the actual cost of development of Multaq, right?

A. That's correct. Had Sanofi provided it, I would have incorporated it.

Q. And you feel good about estimating the amount of cost for Multaq, right?

A. I do.

Q. Okay. So now let's turn over to profits, okay? In your expert report you calculated the profits from the years 2009 to 2014, right?

A. Correct, and I've also considered later years as well.

Q. I'm talking about the opinions you served in your expert report. At that time you only included profit from 2009 to 2014, right?

A. Correct, because the 2015 numbers had not come out yet. I explained that to you at deposition.

Q. Right. You didn't include any profits for 2015, right?

A. Right. They came out after my expert report was served.

Q. Or 2016?

A. Not in my report, but I have considered them in response to arguments from Mr. Tate.

Q. I'm talking about the opinions that you formed in this case and serve in your expert report that you, in your words, used your

best judgment to come to, right? When you served your expert report, you just included profits from 2009 to 2014, right?

A. Yes, for the reasons we've discussed.

Q. You didn't include any future profits in your analysis, right?

A. Not in the NPV analysis. I did consider Multaq's future opportunity.

Q. And in your professional judgment, the appropriate analysis for determining the cost of commercialization is to compare the costs to develop Multaq against the first six years of profitability, right? That was your best judgment?

A. I think one can do that. That evaluates whether Multaq has been a commercial success based on the objective evidence through present day. In addition, as I discussed on my direct, Multaq is unlikely to turn an economic profit even projecting into the future. So the conclusion is the same either way.

Q. We're trying to get to your professional judgment and your opinions you

provided in your expert report. Whether you want to change them after my deposition, that's a different story. As far as your professional judgment when you served your expert report, you just included profits from 2009 to 2014 and did not include any future profits, isn't that right?

A. For the expert report. And to be clear, Plaintiffs had not asserted any future sales in their analysis of commercial success, in Mr. Tate's opening report.

Q. All right. So you didn't include future profits, right? We can agree with that, amongst everything you've said, you have agreed that your professional opinion was only to include profits from 2009 to 2014, right?

A. For limiting to just my NPV analysis in my report, that's true, but of course I included Multaq's future opportunity. I discussed that in my report and in my testimony.

Q. Let's go back and see what the reference is that you rely upon say about how you should do the analysis, all right? Can

we -- we're going to go to JTX-241. If it's not in your book and you want a copy of it, I can hand it up, but perhaps you're familiar with this document. What is this document, JTX-241?

A. This is one of the documents I cite in my expert report. It's called Returns On Research and Development for 1990's New Drug Introductions. You can see the authors here, DiMasi and Grabowski. These are authors that provide some of the widely cited literature on pharmaceutical R and D.

Q. This includes the Grabowski 2002 reference, right?

A. It is, yes.

Q. You're familiar with this article?

A. Yes.

Q. You've relied on it before?

A. I have.

Q. Would it be fair to say you know it inside and out?

A. I know it very well.

Q. Okay. So let's turn to what

Grabowski says is the proper way to do the analysis. Can we turn to page 13? On Page 13 of this article it says our basic procedure is as follows: For each knew drug in our sample worldwide sales profiles are constructed over the drugs product life cycle. Do you see that?

A. I do.

Q. Okay. And now let's turn to page 16. At page 16 under the section that says life-cycle sales profiles it says the next task was to estimate future sales over the complete market life of these products. 20 years was chosen as the expected market life. Do you see that?

A. I do.

Q. You didn't do that in your analysis in your report, did you?

A. No.

Q. Thank you.

A. Because commercial success is a different question.

Q. So you didn't choose 20 years as the expected market life of Multaq, which is what Grabowski says to do, right?

A. I'm sorry?

Q. You didn't use 20 years as the expected market life of Multaq in your analysis which is what Grabowski says to do, right?

A. I didn't use 20 years. We don't know if Multaq will have patent protection that long. That's part of what this litigation is about. Generics could come on the market in two years and those future sales and profits may not materialize. They inherently have some degree of subjective input to them.

Q. But you didn't choose 20 years, did you?

A. No, for the reasons I indicated.

Q. Okay. You didn't make any estimation at all about the future sales of Multaq in your analysis, did you?

A. I have. I presented those to you this morning.

Q. No, I'm talking about in the opinions that you served in your report, not the ones you generated after my deposition. In the report that you generated for this case that was based on your best professional judgment, you

didn't estimate any future sales, did you?

A. I developed those opinions prior to deposition and I explained them to you.

Q. So you developed the opinions and then you didn't include any future sales in your report; is that what you are saying?

A. You're timing is backwards.

Q. Are there any future sales in your expert report?

A. I've already responded no for the reasons we have discussed.

Q. Okay. Thank you. Let's turn to Exhibit 235. Do you recognize this document?

A. I do.

Q. What is it?

A. It's a Cowen and Company market analyst report.

Q. This is one of those equity research documents, right?

A. It is.

Q. It's the kind of document you rely on in your work, right?

A. It is. I believe I cited this one specifically.

Q. But this didn't show up in your direct examination, did it?

A. No.

Q. You cited other equity reports, right?

A. In part, yes.

Q. Okay. This document is dated -- what's the date on this document?

A. September 2015.

Q. All right. And these Cowen equity research people, they were able to forecast future sales for Multaq, right?

A. That's part of their report, yes.

Q. They projected Multaq sales going up to 500 million euros, right?

A. Yes. And as I indicated at deposition, I think that's an optimistic projection, particularly in light of the collection of expert reports that Mr. Tate and I have used for the NPV analysis.

Q. But these Cowen people don't have any relationship to this litigation, do they?

A. Not that I'm aware of.

Q. They've got no incentive to argue

one way or the other, right?

A. Not that I'm aware of.

Q. They were just trying to provide their best information to their investors or whoever it is that receives the equity research, right?

A. That's fair.

Q. They are using their best professional judgment to put out their information, right?

A. You could describe it that way.

Q. All right. So let's turn to page 271, see what they say. They estimate that Multaq sales have, and I think that funny little symbol is euros, right?

A. It is.

Q. 365 million euro in 2015. 415 million euros in 2016. 440 million in 2017. 465 million in 2018 and 515 million in 2020, right?

A. I see that. And as I've indicated, they are quite optimistic. You can see the 26 percent growth in 2015. We know that's wrong. Sales declined in 2015 worldwide,

even more controlling for inflation, so this is too optimistic and inconsistent with the other analyst reports that we've evaluated.

Q. This is one analyst report that suggests that Multaq sales are increasing, right?

A. Yes, but as I've indicated I disagree with what they projected.

Q. You can disagree. I'm not sure you're as unbiased as these equity research people. But one of the other points I think you made in your direct was one of the reasons you believed that there was a limited, I think that was your word, limited outlook for Multaq was because of the regulatory issues with regard to Pallas; is that right?

A. Correct.

Q. So you thought that was going to be a big problem with regard to the sales of Multaq going forward, right?

A. I would expect it to be, and that's borne out in the data which indicate flat sales since 2011.

Q. The references you rely on

characterize the outlook as not being good, right, is that fair to say, the ones you rely on?

A. They say what they say.

Q. They didn't provide any numbers. In your direct testimony, you didn't suggest that actual sales were projected for Multaq from those references, did you?

A. Not the ones we looked at there, but I did consider those in the NPV analysis.

Q. So the references you rely on don't say what the projected sales of Multaq are, that's where we are, right?

A. Well, it depends on what part of the testimony you're asking about.

Q. Well, with regard to Pallas, these people at Cowen, they took Pallas into account, didn't they?

A. Yes, this was after Pallas had been released.

Q. In fact, if you look at the third lineup in the callout, it says despite termination of Pallas, the risk benefit of Multaq remains unchanged. Do you see that?

A. I do.

Q. So these people, who arguably are probably the least biased we've seen, they don't think Pallas has a negative effect, right?

A. I don't know whether they're biased or not, but they are definitely wrong, and you can see that the projections in 2015 are wrong.

Q. Okay. So they took Pallas into account and they believed that Multaq sales were going to go up to 515 million euros in 2002. We can agree on that, right?

A. That's what they say.

Q. Okay. Now, you mention these blocking patent -- the blocking patent and the NCE exclusivity, right?

A. Yes.

Q. And you rely upon your knowledge of patent law and regulatory law for those opinions, right?

A. On my understandings, yes.

Q. Right. If your knowledge of those laws was wrong, then your opinions would not be very strong, would they?

A. Depends on which part, I suppose.
Q. Okay. You don't have a law degree?
A. No.
Q. Never attended law school?
A. No. I'm an economist.
Q. When you search for case law in your current job, you use Google or Google Scholar, right?
A. I do, yes.
Q. You don't use Westlaw?
A. No, we don't have a subscription to that.
Q. You don't use Lexis, right?
A. No.
Q. And you've obtained your understanding of patent law through your professional experience working as an economist who frequently deals with intellectual property issues like patents, right?
A. Yes.
Q. Lawyers have at times explained the law to you?
A. They have.

Q. You also obtained your understanding of patent law from your own reading on the subject and discussions with other professionals that are not attorneys, right?

A. Yes.

Q. You also rely upon phone discussions with your counsel in this case for your understanding of patent law, right?

A. In part. It's one of many factors, yes.

Q. But not the Sandoz or -- not the Defendants that are sitting here right now, right?

A. Not those individuals specifically.

Q. When did you first meet counsel that are at counsel table?

A. It varies by person.

Q. All right.

MR. ROTHMAN: Your Honor, a lot of these questions are legal in nature and we certainly understand that the law is the purview of the Court, but I think as I've demonstrated

his analysis is based on his understanding of the law, so I'm going to be asking him questions that relate to that, not for purposes of educating the Court on the law, but educating the Court on what his understanding is of the law.

THE COURT: Why don't you take a one-minute break and talk to Mr. Solander about how long you're going to be doing this. Go talk to Mr. Solander.

MR. ROTHMAN: Sure.

BY MR. ROTHMAN:

Q. The '510 patent expires in 2016, right?

A. That's my understanding.

Q. And the NCE exclusivity expires in 2014, right?

A. Yes.

Q. And you know that Gilead began developing a competitor Dronedarone product in 2010 during the lifetime of the NCE exclusivity and the patent expiration, right?

A. That's my understanding, it's a combination product.

MR. ROTHMAN: I have nothing further, Your Honor.

THE COURT: Thank you. Any redirect.

MS. CLAYTON: One quick question, Your Honor.

BY MS. CLAYTON:

Q. Doctor McDuff, you were retained on behalf of both Sandoz and Watson for this case; is that right?

A. I was. I was retained on behalf of all of the Defendants.

MS. CLAYTON: Thank you. No further questions.

THE COURT: All right. Doctor McDuff, you may step down.

THE WITNESS: Thank you.

MR. SOLANDER: Just a housekeeping matter.

THE COURT: Okay. Sure.

MR. SOLANDER: During the examination, Mr. McArdle and I communicated through a note. We have agreed to admit JTX-4, which is a certified copy of the '167 file

history.

THE COURT: Okay. All right.

MR. McARDLE: Thank you, Your Honor.

THE COURT: Thank you both.

MS. RURKA: And nothing further from us, Your Honor.

THE COURT: All right. Is there anything more on your side?

MR. SOLANDER: No, Your Honor.

THE COURT: All right. So we'll recess -- actually -- so in any event, so we're done with the evidence. We've decided you're coming back at 3 o'clock to do closing arguments, so I'll see you then. We'll be in recess -- we'll be in recess, but could I just see the various people that were taking things away that I was giving things away at the end of the day yesterday up here for a second? But everybody else pretend I'm gone.

(Luncheon recess.)

State of Delaware)
)
New Castle County)

CERTIFICATE OF REPORTER

I, Stacy Ingram, Registered Reporter, Certified Shorthand Reporter, and Notary Public, do hereby certify that the foregoing record, Pages 808 to 939 inclusive, is a true and accurate transcript of my stenographic notes taken on June 9, 2016, in the above-captioned matter.

IN WITNESS WHEREOF, I have hereunto set my hand and seal this 9th day of June 2016, at Wilmington.

/s/ Dale C. Hawkins

Dale C. Hawkins, RMR